

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA *ex rel.*
DAVID M. KESTER, *et al.*

Plaintiff,

-against-

NOVARTIS PHARMACEUTICALS
CORPORATION, *et al.*

Defendants.

ECF Case

11 Civ. 8196 (CM)

**NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN
SUPPORT OF ITS MOTION TO DISMISS THE SECOND AMENDED COMPLAINT
OF RELATOR DAVID M. KESTER**

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Pursuant to the Court's invitation in its May 29, 2014 Memorandum Decision and Order, -- F. Supp. 2d --, 2014 WL 2324465, at *25 (S.D.N.Y. May 29, 2014) ("*Novartis I*"), and the Court's May 29, 2014 Letter to All Counsel (Dkt No. 191), Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this Memorandum of Law in support of its motion to dismiss the Second Amended Complaint ("SAC" or "Relator's Complaint") brought under the False Claims Act, 31 U.S.C. § 3729 *et seq.* (1994) ("FCA"), and twenty-seven similar state statutes, by relator David Kester ("Relator"). (*See* Dkt. No. 93.)

PRELIMINARY STATEMENT

Incorporating by reference the United States' amended complaint in intervention (the "U.S. Complaint") and the intervening States' complaints in intervention, Relator's Complaint likewise suffers from the same critical legal defect of those complaints: it fails to demonstrate *any* nexus between the alleged "kickback schemes" and the prescriptions for NPC medicines submitted by a specialty pharmacy for government reimbursement. As the Court noted in *Novartis I* when addressing the U.S. Complaint's allegations, if in order to allege an FCA violation an FCA plaintiff must plead some nexus between the prescriptions included in those claims and the alleged kickback scheme, "then the [U.S.] Complaint is deficient." 2014 WL 2324465, at *24. The Court deferred deciding this question of the required nexus to permit the parties to further brief this issue in a motion to dismiss pursuant to Rule 12(b)(6). NPC is filing that motion (the "U.S. Complaint Motion") today concurrently with this motion, and incorporates its arguments here.

As explained in the U.S. Complaint Motion, where FCA claims are based on violations of the Anti-Kickback Statute ("AKS"), they must plead a causal link between the underlying items listed for reimbursement in the claims and the purported kickback. Were the law otherwise, the FCA would punish legitimate claims seeking reimbursement for medically necessary

prescriptions that were not influenced in any way by the supposed “kickback.” As a result, because Relator has not pled any such causal link, Relator’s substantive FCA claims—like the claims of the United States and the intervening States—must be dismissed.

In addition, because Relator’s Complaint fails to state a substantive violation of the FCA, his conspiracy claims must be dismissed as well. In the FCA context, secondary liability for civil conspiracy under 31 U.S.C. § 3729(a)(1)(C) and its predecessor, 31 U.S.C. § 3729(a)(3), cannot exist unless there is a legally cognizable substantive FCA violation. Here, for the reasons set forth in Section I below and in the U.S. Complaint Motion, Relator (like the Government) fails to plead a substantive violation of the FCA, and his conspiracy count should therefore be dismissed as well.

Finally, Relator’s Complaint suffers from two additional defects unique to that pleading. *First*, Relator lacks standing to pursue his claim under the federal FCA in Count 1 as it relates to Myfortic because his allegations are duplicative of the U.S. Complaint. Relator’s Complaint and the U.S. Complaint allege violations of the same three subsections of the FCA; they relate to the same time period from January 2007 to the present; and they are based on the same factual conduct. In fact, Relator’s Complaint expressly incorporates by reference the allegations in the U.S. Complaint. Thus, Relator’s federal claims regarding Myfortic should be dismissed in their entirety as Relator lacks standing to pursue them given that the United States intervened on those allegations. *Second*, several counts of Relator’s Complaint brought under State FCA statutes should be limited to purportedly false claims submitted after the creation of an FCA remedy in that State and to claims submitted within the statute of limitations period. To the extent Relator’s Complaint is not dismissed in its entirety and with prejudice, it should be limited in

scope to those false claims that are actionable and timely, and for which Relator has standing to sue.

ARGUMENT

NPC incorporates this Court’s recitation of the allegations in the U.S. Complaint and Relator’s Complaint in *Novartis I* and *Novartis II*, respectively. For purposes of this motion, NPC accepts, as it must, the allegations in Relator’s Complaint as true. Nothing in this brief, however, should be construed as an admission by NPC of any of the alleged conduct.

I. RELATOR’S COMPLAINT SHOULD BE DISMISSED PURSUANT TO RULE 12(B)(6) BECAUSE IT FAILS TO PLEAD THAT ANY CLAIMS SUBMITTED FOR MYFORTIC, EXJADE, GLEEVEC, TASIGNA, OR TOBI RESULTED FROM THE ALLEGED KICKBACKS PURPORTEDLY PAID BY NPC TO THE SPECIALTY PHARMACIES.

Relator’s Complaint suffers from the same defect as the U.S. Complaint and the complaints filed by the intervening States that Relator incorporates by reference: it fails to allege that the claims for Myfortic, Exjade, Gleevec, Tasigna or TOBI submitted to the government by the specialty pharmacies resulted from the purported kickback schemes. Indeed, the only efforts Relator makes to identify any specific claims that resulted from the alleged schemes is to incorporate by reference the deficient allegations of the Government and State complaints, and to identify ten claims for reimbursement for Exjade submitted by various specialty pharmacies, without any allegation that those ten claims had any connection to an alleged kickback scheme. (*See* SAC ¶¶ 79, 121, 130.)

As set forth in the U.S. Complaint Motion, without an allegation that the alleged “kickbacks” resulted in a patient receiving a particular medication—*i.e.* a Myfortic prescription or a refill of Exjade, Gleevec, Tasigna, or TOBI—because of the corrupting influence of a pharmacy over a doctor or patient, a plaintiff has not pled an actionable FCA claim. Because

Relator has failed to make such an allegation, he has not set forth a cognizable violation of the FCA and his claims pursuant to 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B) must be dismissed.

Moreover, because Relator has failed to state a substantive FCA claim, NPC respectfully submits that his civil conspiracy claims should be dismissed as well, particularly with respect to Gleevec, Tasigna and TOBI. Prior to 2009, the FCA imposed liability on one who “conspires to defraud the Government *by getting a false or fraudulent claim allowed or paid.*” 31 U.S.C. § 3729(a)(3) (emphasis added). Courts, including in the Second Circuit, have interpreted this language to require dismissal of FCA conspiracy claims where there is no underlying substantive violation of the statute. *See, e.g., U.S. ex rel. Vigil v. Nelnet, Inc.*, 639 F.3d 791, 801 (8th Cir. 2011) (“Because the Complaint fails to state claims under sections 3729(a)(1) and (2), it likewise fails to state an actionable conspiracy claim under § 3729(a)(3).”); *U.S. ex rel. Godfrey v. KBR, Inc.*, 360 Fed. App’x 407, 2010 WL 55510, at *5 (4th Cir. Jan. 6, 2010) (since conspiracy claim is premised on dismissed claims of underlying FCA violations, the conspiracy claim fails along with the individual FCA claims); *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d. 313, 336 (S.D.N.Y. 2004) (dismissing FCA conspiracy claims where substantive FCA claims were dismissed); *U.S. ex rel. Potra v. Jacobson Cos., Inc.*, 12 Civ. 1600, 2014 WL 1275501, at *4 (N.D. Ga. Mar. 27, 2014) (“Because the Relators have failed to state an FCA claim, their claim that the Defendants allegedly conspired to violate the FCA necessarily fails.”); *U.S. ex rel. Phillips v. L-3 Communications Integrated, Sys.*, No. 10-CV-1784, 2012 WL 3649699, at *8 (N.D. Tex. Aug. 24, 2012) (dismissing civil conspiracy claim when no actionable FCA claim because “a claim for civil conspiracy is generally not viable without the commission of any underlying wrongful act,” and “because there is no actionable FCA claim . . . [the] civil conspiracy claim fails.”); *U.S. ex rel. Coppock v. Northrup Grumman Corp.*, No. 98 Civ. 2143,

2003 WL 21730668, at *14 n. 17 (N.D. Tex. July 22, 2003) (noting that “secondary liability for conspiracy under § 3729(a)(3) cannot exist without a viable underlying claim,” because “[a] claim for civil conspiracy is generally not viable without the commission of an underlying wrongful act”).

In 2009, the conspiracy provision of the FCA was amended to its present formulation, which imposes liability on one who “conspires to commit a violation” of the other liability sections of the statute. 31 U.S.C. § 3729(a)(1)(C). NPC submits that conspiracy claims alleged pursuant to the amended version of the FCA still rise and fall with the sufficiency of the underlying violation. In *Novartis I and II*, this Court recognized that “[b]ecause conspiracy is an inchoate crime, the plaintiff need not prove that the defendant actually achieved the object of the conspiracy and *completed* a substantive FCA violation” *Novartis I*, 2014 WL 2324465, at *25 (emphasis added); *Novartis II* at 18 (emphasis added). But, as the Court also noted, a plaintiff still must plead adequately “an unlawful agreement by the defendant to violate the FCA.” *Id.* (citing *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 193 (5th Cir. 2009), *U.S. ex rel. Sterling v. Health Ins. Plan of Greater N.Y., Inc.*, No. 06 Civ. 1141, 2008 WL 4449448, at *4 (S.D.N.Y. Sept. 30, 2008)). Thus, although a civil conspiracy under the post-2009 FCA does not require the submission of a false claim, it does require sufficient allegations that the defendant agreed to commit a substantive violation of the FCA. *See Potra*, 2014 WL 1275501, at *4 (“Because the Relators have failed to state an FCA claim, their claim that the Defendants allegedly conspired to violate the FCA necessarily fails.”).

Here, although the Relator cites to both the pre and post-2009 statute, his FCA conspiracy allegations track the language of the pre-2009 version of the statute. Specifically, Relator alleges that NPC unlawfully conspired to defraud the government “by getting false or fraudulent claims

allowed or paid.” (SAC ¶ 136). Accordingly, and consistent with the cases cited above, Relator must allege a viable underlying FCA violation in order for his conspiracy claims to stand. With respect to Gleevec, Tasigna and TOBI, this Court already has held in *Novartis II* that the Relator failed to plead a scheme to defraud with the requisite particularity: “[T]he Relator does not provide any factual basis to support his assertion that Novartis actually caused any pharmacy to submit claims for Gleevec, Tasigna, or TOBI to the government.” Therefore, Relator does not allege a viable FCA violation with respect to these three drugs and his related conspiracy claims should be dismissed.

Additionally, for the reasons stated in Section I and the U.S. Complaint Motion, the Relator also has not pleaded a substantive violation of the FCA for any drug included in his Complaint, because he fails to allege the necessary causal link between the alleged kickbacks NPC purportedly paid to specialty pharmacies and the prescribing decisions of physicians which resulted in claims for reimbursement for the five drugs at issue (three of which—Gleevec, TOBI, and Tasigna—already have been dismissed on Rule 9(b) grounds, as mentioned above). To the extent NPC prevails on this argument and Relator’s substantive FCA claims are dismissed on Rule 12(b)(6) grounds, then his conspiracy claims should be dismissed as well. This argument applies with equal force to Relator’s conspiracy claims arising under each of the 27 state FCA analogues, and conspiracy claims in the U.S. Complaint.

II. RELATOR’S MYFORTIC ALLEGATIONS ON BEHALF OF THE FEDERAL GOVERNMENT SHOULD BE DISMISSED BECAUSE THEY ARE DUPLICATIVE OF THE MYFORTIC ALLEGATIONS IN THE U.S. COMPLAINT.

Courts in this District and throughout the country have uniformly held that a relator lacks standing to pursue claims that are duplicative of the ones the United States asserts in intervention. *See U.S. ex rel. Feldman v. City of New York*, 808 F. Supp. 2d 641 (S.D.N.Y.

2011) (“when the Government decides to intervene in a *qui tam* action, the Government’s claims become the operative claims insofar as they are duplicative of those of the relator.”); *see also* *U.S. ex rel. Badr v. Triple Canopy, Inc.*, 950 F. Supp. 2d 888, 895 n.1 (E.D. Va. 2013); *U.S. ex rel. Robinson-Hill v. Nurses’ Registry & Home Health Corp.*, Civ. A. 08-145, 2012 WL 4598699, at *9 (E.D. Ky. Oct. 2, 2012), *reconsideration denied*, Civ. A. 08-145, 2013 WL 1184370 (E.D. Ky. Mar. 20, 2013); *U.S. ex rel. Allen v. Guidant Corp.*, Civ. 11-22, 2012 WL 878023, at *6 (D. Minn. Mar. 14, 2012); *United States ex rel. Magee v. Lockheed Martin Corp.*, CIV. 09-CV-0324, 2010 WL 972214, at *3 (S.D. Miss. Mar. 12, 2010).

Here, Count 1 of Relator’s Complaint as it relates to Myfortic is duplicative of the U.S. Complaint. Relator’s Complaint and the U.S. Complaint allege violations of the same three subsections of the FCA; they relate to the same time period from January 2007 to the present; and Relator’s factual allegations relating to Myfortic are substantively duplicative of the allegations relating to Myfortic in the U.S. Complaint. (*Compare, e.g.,* SAC ¶ 121 (incorporating by reference Myfortic allegations in U.S. Complaint); *id.* ¶¶ 122-127 (generally alleging that NPC used rebates and discounts to grow Myfortic market share) *with* U.S. Compl. ¶¶ 61, 127 (same).) Thus, while Relator is obviously free to pursue his Myfortic claims on behalf of states that chose not to intervene, provided that the state FCAs permit the Relator to do so, his federal claim as it relates to Myfortic should be dismissed.

III. RELATOR’S CLAIMS UNDER SEVERAL STATE FALSE CLAIMS ACTS SHOULD BE LIMITED TO CLAIMS SUBMITTED AFTER RELATOR HAD A REMEDY UNDER THOSE STATUTES OR WITHIN THE LIMITATIONS PERIOD.

A. Relator’s Claims Under Several State False Claims Acts Should Be Limited To Claims Submitted After Relator Had A Remedy Under Those Statutes.

There is a “general presumption that legislation is intended to operate prospectively” unless clearly and manifestly intended by the legislature. *See, e.g., Enfield Fed. Sav. & Loan*

Ass'n v. Bissell, 440 A.2d 220, 221 (Conn. 1981) (retroactive application must be “clearly and unequivocally expressed”); *Cole v. Silverado Foods, Inc.*, 78 P.3d 542, 546 (Okla. 2003) (noting that “[a]bsent a plain legislative intent to the contrary, statutes are generally presumed to operate prospectively only” unless they are strictly procedural); *Direct Action for Rights & Equality v. Gannon*, 819 A.2d 651, 658 (R.I. 2003) (noting presumption “that statutes and their amendments operate prospectively unless there is clear, strong language or a necessary implication that the General Assembly intended to give the statute retroactive effect.”). In addition, “legislation which affects substantive rights may only operate prospectively.” *Fowler Props., Inc. v. Dowland*, 646 S.E.2d 197, 200 (Ga. 2007).

This fundamental principle has been applied in the context of State FCA statutes. *See United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 605 (E.D. Pa. 2012) (FCA statutes of Connecticut, Georgia, New York, Oklahoma, and Rhode Island cannot be applied retroactively); *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 532 (S.D. Tex. 2011) (refusing to apply retroactively the FCA statute of Connecticut and Minnesota), *order vacated in part on other grounds on reconsideration*, CIV. A. 06-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012); *State ex rel. Hayling v. Corr. Med. Servs., Inc.*, 28 A.3d 1246, 1251 (N.J. Super. Ct. App. Div. 2011) (noting that the New Jersey “[l]egislature declined to follow the model of some other states, which specified that their false claims acts would have retroactive application”).

Here, Relator asserts that “[t]he false claims that form the basis for the Defendants’ liability . . . include all claims for Exjade, Gleevec, Tasigna, TOBI and Myfortic that have been billed by a specialty pharmacy to Medicare, Medicaid or another government health care program” *since January 2007*. (SAC ¶¶ 52, 128.) However, the FCA statutes of Connecticut,

Georgia, Minnesota, New Jersey, Oklahoma, and Rhode Island were all enacted *after* the beginning of the alleged “kickback” period and do not contain retroactivity provisions. *See* Conn. Gen. Stat. Ann. § 17b-301f (Connecticut FCA became effective in relevant part on October 5, 2009); Ga. Code Ann. §§ 49-4-168 to -168.6 (Georgia FCA became effective on May 24, 2007); Minn. Stat. 15C.01 to 15C.14 (Minnesota FCA became effective on July 1, 2010); N.J. Stat. Ann. §§ 2A:32C-1 to -18 (New Jersey FCA became effective on March 13, 2008); Okla. Stat. tit. 63, §§ 5053.1 to 5053.7 (Oklahoma FCA became effective on November 1, 2007); R.I. Gen. Laws §§ 9-1.1-1 to 9-1.1-9 (Rhode Island FCA became effective on July 1, 2007). The law of these states is clear that these FCA statutes—which affect substantive rights but contain no express provision for retroactivity—cannot be retroactively applied.

Moreover, retroactive application of punitive State FCA statutes that include penalties and treble damages provisions would violate the *Ex Post Facto* Clause. *See Louis Vuitton S.A. v. Spencer Handbags Corp.*, 765 F.2d 966, 971-72 (2d Cir. 1985) (“Retroactive application of the treble damages provision [of trademark law] could raise constitutional questions concerning both the *Ex Post Facto* Clause . . . and the Due Process Clause,” finding “exclusively prospective application” of a civil statute that imposes treble damages “as the better course”); *State ex rel. Grupp v. DHL Express (USA), Inc.*, 970 N.E.2d 391, 397 (N.Y. 2012) (“[R]ather than redressing the harm actually suffered, the [New York FCA’s] *imposition of civil penalties and treble damages evinces a broader punitive goal of deterring fraudulent conduct against the State.* Thus, instead of compensating the State for damages caused by [defendant’s] purported scheme and addressing its narrow proprietary interests, the FCA would punish and consequently deter such future conduct, thereby promoting a general policy.”) (emphasis added).

Accordingly, although the FCA statutes of Maryland and Wisconsin were enacted after the beginning of the “kickback” period alleged in Relator’s Complaint, and do contain retroactivity provisions,¹ claims regarding conduct pre-dating the enactment of these statutes should be dismissed because retroactive application of these FCA statutes which include penalties and treble damages provisions would violate the *Ex Post Facto* Clause. *See Grupp*, 970 N.E.2d at 397. Because a retroactive application of these statutes would go beyond compensating the State for damages caused by defendants’ purported scheme and punish such conduct, they should not be retroactively applied.

Courts have reached different conclusions as to whether the New York FCA should be applied retroactively. *Compare People ex rel. Schneiderman v. Sprint Nextel Corp.*, 970 N.Y.S.2d 164, 173-76 (N.Y. Sup. Ct. 2013) (allowing retroactive application of the 2010 amendments to the New York FCA), *aff’d* 980 N.Y.S.2d 769, 770 (App. Div. 1st Dep’t 2014), *with U.S. ex rel. Romano v. N.Y.-Presbyterian Hosp.*, No. 00-8792, 2008 WL 612691, at *2 (S.D.N.Y. Mar. 5, 2008) (“The New York False Claims Act itself has no express statutory grant of retroactivity.”), *and King*, 823 F. Supp. 2d at 529 (finding “no reason to apply the [New York FCA] to claims arising before April 1, 2007”). NPC respectfully submits that the *Romano* and *King* decisions were correctly decided and the *Sprint* decision is inconsistent with the finding by the New York Court of Appeals in *Grupp* that the New York FCA is punitive in nature.

Furthermore, prior to May 4, 2007, the Texas FCA statute required dismissal of a *qui tam* relator’s claims if the State of Texas did not intervene. While the May 4, 2007 amendment subsequently allowed relators to pursue non-intervened claims, courts have found that a relator

¹ *See* Md. Code Ann., Health-Gen. §§ 2-601 to 2-611 (Maryland FCA became effective on October 1, 2010); Md. Code Ann., Health-Gen. § 2-609(b) (retroactivity provision); Wis. Stat. § 20.931 (Wisconsin FCA became effective on October 27, 2007); Wis. Stat. § 20.931(15) (retroactivity provision).

cannot pursue non-intervened claims for conduct occurring prior to May 4, 2007. *See, e.g., Streck*, 894 F. Supp. 2d at 604-05 (citing cases). Accordingly, Relator's Texas FCA claim should be limited to the period after May 4, 2007. *See, e.g., id.*

B. Relator's Twentieth Count Under The New Mexico State FCA Statute Should Be Limited To Claims Submitted After November 14, 2007.

Relator's claim pursuant to the New Mexico FCA is subject to a four-year statute of limitations. *See, e.g.,* N.M. Stat. Ann. §§ 27-14-13(A), 37-1-4 (four-year residual statute of limitations applies to claims under state FCA). Relator filed his complaint on November 14, 2011. Therefore, his claims under the New Mexico FCA statute should be limited to claims submitted after November 14, 2007.

In summary, Relator's claims, to the extent they are not dismissed in their entirety for the reasons set forth in Section I, *supra*, should be dismissed with prejudice to the extent they relate to conduct occurring before the dates below:

<u>Count</u>	<u>State</u>	<u>Date</u>	<u>Count</u>	<u>State</u>	<u>Date</u>
Four	Connecticut	Oct. 5, 2009	Twenty-One	New York	Apr. 1, 2007
Eight	Georgia	May 24, 2007	Twenty-Three	Oklahoma	Nov. 1, 2007
Thirteen	Maryland	Oct. 1, 2010	Twenty-Four	Rhode Island	July 1, 2007
Sixteen	Minnesota	July 1, 2010	Twenty-Six	Texas	May 4, 2007
Nineteen	New Jersey	Mar. 13, 2008	Twenty-Eight	Wisconsin	Oct. 27, 2007
Twenty	New Mexico	Nov. 14, 2007			

CONCLUSION

For the foregoing reasons, the Court should dismiss Relator's Complaint in its entirety.

Dated: June 13, 2014

Respectfully submitted,

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